



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,498	08/02/2006	Ronald Rodriguez	59563(71699)	3398
49383 7590 10/02/2007 EDWARDS ANGELL PALMER & DODGE LLP Client: JHU P.O. BOX 55874 BOSTON, MA 02205				
			EXAMINER GUDIBANDE, SATYANARAYAN R	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 10/02/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/523,498

Applicant(s)

RODRIGUEZ ET AL.

Examiner

Satyanarayana R. Gudibande

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8 and 28-34 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 is/are allowed.
- 6) ☒ Claim(s) 28-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some \* c) ☐ None of:
    - 1. ☐ Certified copies of the priority documents have been received.
    - 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's request for reconsideration of the finality (abandonment) of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. Prosecution is reopened to continued examination of the application.

#### ***Election/Restrictions***

Applicant's election without traverse of group II invention and SEQ ID NO: 1 as the species and in the reply filed on 12/08/06 was acknowledged in office action dated 1/22/07.

Applicant's amendment to claims in the response filed on 7/13/07 has been acknowledged.

Claims 8 and 28-34 are pending.

Claims 8 and 28-34 are examined on the merit.

Any objections and rejections made in the previous office action dated 1/22/07 not specifically mentioned here are considered withdrawn.

#### ***Maintained Rejections***

##### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28 and 34 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as stated in the office action dated 1/22/07.

Applicants argue that “[A]mino acid analogs are well know in the art such that one of ordinary skill routinely uses them in the course of research. In fact, many companies are focused on selling amino acid analogs. For example, Peptech Corp. (Burlington, MA) has a **wide variety of specific amino acid analogs** (emphasis added by Examiner) that can be ordered by the ordinary skilled artisan. Their catalog sets forth **numerous analogs for a variety of natural amino acids** (emphasis added by Examiner). One of ordinary skill in the art could easily use these amino acid analogs in the claimed peptides.

Moreover, the Examiner states that it is not clear how many of the analogs are used and at which positions they are used. However, as amino acid analogs are routinely used in the art, the ordinary skilled artisan would be able to make the claimed peptides containing analogs. The ordinary skilled artisan could then determine if the peptides fall with in the scope of the claim by using the functional assays described in the specification to test if the peptides selectively binds to the extracellular portion of human PSMA.

Accordingly, Applicants believe that the ordinary skilled artisan would find the claimed compounds to be described by the specification as filed. Applicants respectfully request that the Examiner reconsider and withdraw the foregoing rejection”.

Applicant's arguments filed 7/13/07 have been fully considered but they are not persuasive. Because, as stated by applicants in their response, innumerable modifications can be made to each amino acid to create infinite number of analogs. The incorporation of these infinite number of modified amino acids into peptides at any and all positions leads to number of analogs represents countless number of peptides and therefore, the claim as recited as treated being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

***Withdrawn Rejections***

***Claim Rejections - 35 USC § 102***

Applicant's arguments and amendments claims 28 and 29, see page 3, filed 7/13/07, with respect to the rejection(s) of claim(s) 28-30, 32 and 33 under ***35 USC § 102*** have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of amendments claims 28 and 29 that introduces new matter.

However, in the event the new matter is vacated and the claims are restored to as originally presented by the applicant, the withdrawn rejection will be re-instated and maintained.

***New grounds of rejections***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

Art Unit: 1654

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended to recite a phrase “within a linear span of 7 amino acid residues.”

#### ***Lack of Ipsis Verbis Support***

The specification lacks any Ipsis Verbis support that would support the phrase “within a linear span of 7 amino acid residues”. Applicants state that the support for the amendment to the claims can be found throughout the specification. Applicant’s statement for the support for the amendment is not persuasive and **no literal support** for the amendment as recited is available in the specification.

#### ***Lack of Implicit Support***

It is acknowledged that there is it should be noted, that exact terms need not be used *in haec verba* to satisfy the written description requirement of the first paragraph of 35 U.S.C. 112. Newly added claims or amendment can be supported by implicit, or inherent disclosure. However, the specification also lacks any implicit or inherent disclosure that would imply support for the phrase “within a linear span of 7 amino acid residues”. To the contrary, the specification teaches “a peptide having consensus sequence has at least 1, 2, 3, 4, 5, 6, or most

Art Unit: 1654

preferably, 7 amino acid residues in common with the consensus sequence” (page 7, lines 18-19, lines 24-25 and page 8 lines 4-5). This definition does not translate into claim as recited with the phrase “within a linear span of 7 amino acid residues”.

The meaning of “a peptide having consensus sequence has at least 1, 2, 3, 4, 5, 6, or most preferably, 7 amino acid residues in common with the consensus sequence” would be interpreted as that “**any 1, 2, 3, 4, 5, 6, or most preferably, 7 amino acid residues are common** with the consensus sequence of the peptide” and **not in a linear span of 7 amino acids** as recited in the claim.

In conclusion, the specification does not provide reasonable support to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention as amended.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Misawa, 1998, Biochemical and biophysical research communications, 244, 531-539.

In the instant application, applicants claim a peptide compound which selectively binds to the extracellular portion of human PSMA and comprises at least 5 residues of the consensus

Art Unit: 1654

sequence QKHHNYL (SEQ ID NO: 109), wherein the 5 residues are within a linear span of 7 amino acid residues.

Misawa, et al., discloses a peptide sequence KHHNY within a linear span of 7 amino acid residues (page 534, figure 1, panel A, amino acid residues 63-67). Since the reference discloses the peptide sequence KHHNY within a linear span of 7 amino acid residues in a peptide it is inherent that the peptide of the cited reference selectively binds to the extracellular portion of human PSMA. Therefore, the cited reference anticipates the instant invention.

Claim 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Alfonso, 2000, Journal of Virology, 74(8), 3815-3831, as evidenced by the search results from Registry database that shows the peptide sequence of flowpox virus gene FPV221.

In the instant application, applicants claim a peptide compound which selectively binds to the extracellular portion of human PSMA and comprises at least 5 residues of the consensus sequence QKHHNYL (SEQ ID NO: 109), wherein the 5 residues are within a linear span of 7 amino acid residues or the consensus sequence QKHHNYL (SEQ ID NO: 109), wherein the 6 residues are within a linear span of 7 amino acid residues.

Alfonso, et al., discloses a peptide sequence KHHNYL within a linear span of 7 amino acid residues (page 3821, table 1) the sequence KHHNYL is depicted on the results page of Registry database, amino acid position 29-34. Since the reference discloses the peptide sequence KHHNYL within a linear span of 7 amino acid residues in a peptide it is inherent that the peptide of the cited reference selectively binds to the extracellular portion of human PSMA. Therefore, the cited reference anticipates the instant invention.



Art Unit: 1654

Applicant's amendment to claims 28 and 29 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Allowable Subject Matter***

Claim 8 is allowed.

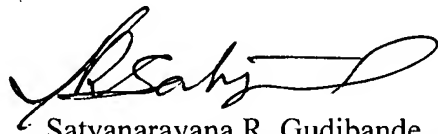
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

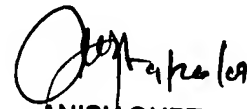
Art Unit: 1654

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Satyanarayana R. Gudibande, Ph.D.  
Art Unit 1654



ANISH GUPTA  
PRIMARY EXAMINER